

### **REMARKS/ARGUMENTS**

Applicants have carefully reviewed the Office Action mailed on January 19, 2010, prior to preparing this response. Currently, claims 1-4, 6-34, 43, 73-78, and 82-96 are pending in the application and have been rejected. Claims 43, 94 and 95 have been amended and claim 96 has been cancelled with this paper. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

#### **Claim Rejections under 35 U.S.C §103**

Claims 1-4, 6-18, 20-29, 31, 33, 34, 43, 73-78, 82-84, and 88-96 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel (U.S. Patent No. 4,796,629) in view of Vigil et al. (U.S. Patent No. 5,336,234). Applicants respectfully traverse this rejection.

In formulating the rejection, the stiffening member 1050 of Grayzel was equated to the claimed discrete strip of a second material of claim 1. While referring to lines 14-23 of column 6 of Grayzel, it was stated in the Office Action that the striped portions 1050 of Grayzel run the length of the balloon. Applicants respectfully disagree with this understanding of this passage of Grayzel. Applicants assert Grayzel expressly states that the stiffening members, including the stiffening member 1050 shown in FIG. 10, are only intended to extend through the central cylindrical section of the balloon.

Turning first to the paragraph of Grayzel beginning at line 49 of column 4, it is stated:

The middle portion 46 of the balloon is cylindrical in shape and of relatively uniform and continuous surface. This is the portion of the device which is intended to press upon the stenotic structure to dilate the same by expansion of the balloon. As seen in FIGS. 2 and 3, embedded in the skin 42 of the balloon is a stiffening member 50, which is intended to run the length of the cylindrical section of the balloon or the contacting section of the balloon. This need not necessarily extend from the arcuate front 42 to the arcuate rear 48; but could be shorter. In all likelihood, it would not be longer than the contacting surface, since the stiffening member should be straight in order to minimize the cross-sectional area of the balloon when in the unexpanded or contracted state. The stiffening members 50 have rounded corners 52 so that there will be no sharp edges that would tend to form stress concentration points or initiate rips or stretches in the skin 42 of the catheter device. The skins are usually made from a relatively thin flexible but usually not elastic plastic.

Thus, it can be seen that Grayzel contemplated that the stiffening member could extend the full length of the cylindrical section, but would not be longer than the contacting surface. Thus, Grayzel states the stiffening member may extend from the point where the middle portion 46 (i.e., the cylindrical shaped portion) meets the arcuate front 42 to the point where the middle portion 46 meets the arcuate rear 48, but does not extend into the arcuate front and rear portions 42, 48. This is consistent with the statement of Grayzel that the stiffening member may “extend from the arcuate front 42 to the arcuate rear 48”. Grayzel, at col. 4, lines 57-58. It is noted that Grayzel does not state that the stiffening member extends into the arcuate front 42 or extends into the arcuate rear 48 portions of the balloon.

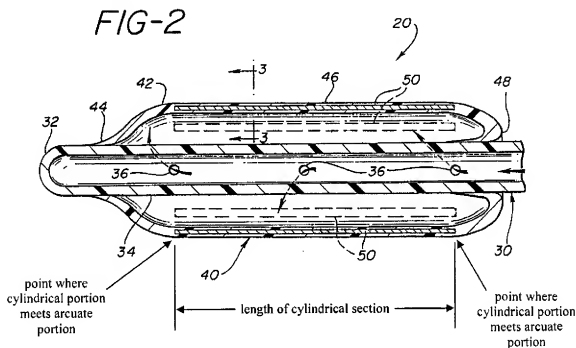


FIG. 2 of Grayzel, reproduced above, shows the stiffening member 50 extending the full length of the cylindrical section, but the stiffening member 50 does not extend into either the proximal arcuate portion 48 (equated to the claimed first tapered portion) or the distal arcuate portion 42 (equated to the claimed second tapered portion). Thus, Grayzel teaches that the stiffening member 50 extends no further than the extents of the cylindrical section.

The teachings of Grayzel at lines 14-23 of column 6, referenced in formulating the rejection, do not contradict this teaching of Grayzel. This passage of Grayzel, which is

reproduced below, discusses advantages of the tapered end portions of the stiffening member 1050 shown in FIG. 10. This passage states:

The tapering of the ends of the stiffening member, as shown at 12 and 13, reduces the trauma on the balloon as the balloon moves from its central cylindrical shape towards the end of the balloon where it tapers down to be joined with the wall of the catheter. By having the ends of the stiffening members tapered, they are less rigid and therefore more able to conform to the shape of the balloon at the end of the stiffener thereby reducing the discontinuity of stiffness and/or flexibility between the stiffener and the skin of the balloon.

This passage says nothing regarding the stiffening member 1050 extending into the arcuate portions 42, 48 of the balloon, but rather tapering of the end portions of the stiffening member 1050 in order to more gradually reduce the discontinuity of stiffness and/or flexibility of the balloon at the ends of the stiffening member 1050. This passage only refers to the fact that the stiffness of the balloon decreases along the balloon as one moves from the central portion of the balloon towards the tapered or arcuate portions 42, 48 of the balloon. Namely, the sentence of Grayzel, at col. 6, lines 14-18 more accurately reads as "The tapering of the ends of the stiffening member, as shown at 12 and 13, reduces the trauma on the balloon as the balloon moves from [the balloon's] central cylindrical shape towards the end of the balloon where [the balloon] tapers down to be joined with the wall of the catheter." Thus, Grayzel appears to teach the tapered ends of the stiffening member 1050 extend toward the ends of the cylindrical portion to where the balloon tapers (i.e., the arcuate portions 42, 48). This passage does not teach that the tapered end portions of the stiffening member 1050 extend into the arcuate portions 42, 48.

Furthermore, returning to the passage of Grayzel at column 4, Grayzel states, "[t]he stiffening member should be straight in order to minimize the cross-sectional area of the balloon when in the unexpanded or contracted state." Grayzel, at col. 4, lines 60-63. Thus, Grayzel teaches away from extending the stiffening member into the arcuate portions, as such a configuration would require the stiffening member to be other than straight.

The teachings of Vigil et al. at least fail to remedy the noted shortcomings of Grayzel. Namely, Vigil fails to teach a discrete strip of a second material extending continuously along a body portion of a balloon into a first tapered portion and into a second tapered portion, as currently claimed. For at least these reasons, claim 1 is believed patentable over the cited

combination. Claims 2-4, 6-13, 73, 76, 82, 88-89 and 94, which depend from claim 1 and add additional limitations are also believed patentable over the cited combination. Withdrawal of the rejection is respectfully requested.

Claim 14, recites "the discrete striped portion extending continuously along the body portion of the balloon, at least a portion of the first tapered portion, and at least a portion of the second tapered portion. As noted above, Grayzel teaches that the stiffening member 1050 extends no further than the extents of the cylindrical section, and thus does not extend along any portion of the proximal arcuate portion 48 or the distal arcuate portion 42 of the balloon of Grayzel. Vigil et al. fails to remedy the noted shortcomings of Grayzel.

For at least these reasons, claim 14 is believed patentable over the cited combination. Claims 15-18, 20-29, 31, 33, 34, 74, 77, 83, 90-91 and 95, which depend from claim 14 and add additional limitations are also believed patentable over the cited combination. Withdrawal of the rejection is respectfully requested.

Claim 43 recites that the discrete striped portion extends continuously from the first end of the inflatable balloon to the second end of the inflatable balloon such that the discrete striped portion extends through each of the first sleeve portion, the first tapered portion, the body portion, the second tapered portion, and the second sleeve portion. The cited combination fails to teach such a configuration. Namely, as noted above, Grayzel teaches that the stiffening member 1050 extends no further than the extents of the cylindrical section, and thus does not extend entirely through the balloon from the first end of the balloon to the second end of the balloon. As shown in FIG. 2 of Grayzel, the tapered or arcuate portions of the balloon are devoid of the stiffening member 50. Vigil et al. fails to remedy the noted shortcomings of Grayzel.

For at least these reasons, claim 43 is believed patentable over the cited combination. Claims 75, 78, 84 and 92-93, which depend from claim 43 and add additional limitations are also believed patentable over the cited combination. Withdrawal of the rejection is respectfully requested.

Claims 30 and 85-87 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel (U.S. Patent No. 4,796,629) in view of Vigil et al. (U.S. Patent No. 5,336,234)

as applied to claims 1, 14, and 43 above, and further in view of Roychowdhury (U.S. Patent No. 5,587,125). Applicants respectfully traverse this rejection.

Claims 30 and 85-87 depend from one of independent claims 1, 14 and 43, and add additional limitations. For at least the reasons stated above, the cited combination of Grayzel and Vigil et al. fails to render these claims obvious. The teachings of Roychowdhury fail to remedy the shortcomings of Grayzel and Vigil et al. For at least this reason a prima facie case of obviousness has not been established. Withdrawal of the rejection is respectfully requested.

Claim 32 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel (U.S. Patent No. 4,796,629) in view of Vigil et al. (U.S. Patent No. 5,336,234) as applied to claim 14 above, and further in view of Spears (U.S. Patent No. 5,082,841). These rejections are respectfully traversed. Applicants respectfully traverse this rejection.

Claim 32 depends from independent claim 14, and adds additional limitations. For at least the reasons stated above, the cited combination of Grayzel and Vigil et al. fails to render claim 14 obvious. The teachings of Spears fail to remedy the shortcomings of Grayzel and Vigil et al. For at least this reason a prima facie case of obviousness has not been established. Withdrawal of the rejection is respectfully requested.

**Conclusion**

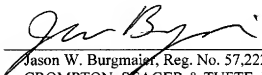
Further examination and withdrawal of the rejections are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Lixiao Wang et al.

By their attorney,

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Jason W. Burgmaier, Reg. No. 57,222  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349